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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,662	10/26/2001	Thomas J. Shaw	75329/81138	4884
7590	01/13/2004			EXAMINER
Monty L. Ross Locke Liddell & Sapp LLP Suite 2200 2200 Ross Avenue Dallas, TX 75201-6776				SIRMONS, KEVIN C
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 01/13/2004	5

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/047,662	SHAW ET AL.
	Examiner	Art Unit
	Kevin C. Sirmons	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 26 October 2001.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-66 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 46-58 and 61-66 is/are allowed.  
 6) Claim(s) 1-27,33-38,41,44,45,59 and 60 is/are rejected.  
 7) Claim(s) 28-32,39,40,42 and 43 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                            5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                            6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "20" and "80" have both been used to designate a hub. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It appears that the figure lack a showing of a catheter.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: See a retraction mechanism (claim1); an insert molded needle (claim 15).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, applicant claimed that the tubular body comprises an outwardly facing annular recess proximal to the plunger tube, however, it appears from the drawings that the tubular body has an outwardly facing annular recess at least distal to the plunger tube.

Therefore, it is unclear whether the annular recess is proximal or distal the plunger tube.

Furthermore, it is the examiner's position that the annular recess is neither proximal nor distal the plunger tube.

As to claim 1, it is unclear if the annular recess and annular boss are biased into releasable engagement with each other or some other structure.

As to claims 15 and 38, it is unclear what is meant by insert-molded needle.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 14-16, 23-24, 59, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw U.S. Pat. No. 5,817,058.

Shaw discloses an IV catheter introducer comprising: a tubular housing (16); a needle holder assembly (14) having a tubular body slidably engaged inside the housing (fig. 1); a retraction mechanism seated in annular space between the housing and the needle holder assembly (figs. 6 and 7); a plunger assembly (18) having a plunger tube releasably engaged with the tubular body inside the housing (fig. 6); and a catheter attached by frictional engagement to the tubular housing (54); the tubular body comprises an outwardly facing annular recess proximal to the plunger tube (42); the plunger tube comprises an outwardly extending annular boss proximal to the tubular body (64); and the annular recess and annular boss are biased into

releasable engagement (figs. 6); as to claims 2-3, (50); as to claims 4 and 5, (col. 7, lines 12-27); as to claim 14, (fig. 6); as to claims 15-16, (figs. 1, 8 and col. ); as to claim 23, (16); as to claim 24, (56); as to claims 59 and 60, (see above rejection).

Claims 25-26, 33-37, 41, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Botich et al U.S. Pat. No. 6,096,005.

Botich discloses an IV catheter introducer comprising: a tubular housing (622); a needle holder assembly (656) having a tubular body (625) slidably engaged inside the housing (fig. 11-13); a retraction mechanism (633) seated in an annular space between the housing and the needle holder assembly (figs. 11-13); a plunger assembly (624) having a plunger tube releasably engaged with the tubular body inside the housing (figs 11-13); and a catheter attached by frictional engagement to the tubular housing (700); the plunger tube comprises a vented end that is opposite the tubular body (757); as to claim 26, (757); as to claims 33-38, 41, (figs. 11-13); as to claims 44 and 45, (fig. 11).

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw U.S. Pat.

No. 5,817,058.

Shaw discloses the IV catheter introducer substantially as claimed except for a needle sonically welded into the needle holder assembly. Shaw discloses a needle molded and/or glued to the needle holder assembly. Therefore, it would have been an obvious matter of design choice to connect the needle to the needle holder assembly, since such a modification would have involved common knowledge of someone of ordinary skill in the art. Furthermore, applicant has not disclosed that sonically welding a needle to a needle holder assembly solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the connection process as taught by Shaw.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw U.S. Pat. No. 5,817,058 in view of Shaw et al U.S. Pat. No. 5,989,220.

Shaw discloses an IV catheter introducer substantially as claimed except for a needle holder assembly that has a needle with an end that extends into the flash chamber. Shaw et al discloses a needle holder assembly that has a needle with an end that extends into the flash chamber (fig. 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle as taught by Shaw with the needle with an end that extends into the flash chamber as taught by Shaw et al, in order to drain fluid from the chamber.

Additionally, it would have been an obvious matter of design choice to make a needle holder assembly that has a needle with an end that extends into the flash chamber, since applicant has not disclosed that having the needle extending into the flash chamber solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device as taught by Shaw.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al U.S. Pat. No. 6,096,005.

Botich discloses an IV catheter introducer substantially as claimed except for a plastic end cap that is colored. It would have been an obvious matter of design choice to change the color of the end cap, since it is notoriously well known that such a modification would have involved a mere change in color of a component. A change in color is generally recognized as being within the level of ordinary skill in the art. Further, applicant has not disclosed that having a colored end cap is for any particular purpose and it appears that the invention would perform equally well with the device as taught by Botich.

***Allowable Subject Matter***

Claims 28-32, 39-40 and 42-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 6-13 and 19-22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

Claims 46-58 and 61-66 are allow over the prior art of record.

*Conclusion*

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

*KCS*  
Kevin C. Sirmons  
Patent Examiner  
1/7/04